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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gary B. McAlister

Serial No.: 10/679,563 Examiner: Unknown

Filed: October 6, 2003 Group Art Unit: Unknown

For: RETRIEVAL DEVICE MADE OF PRECURSOR ALLOY CABLE

Docket No.: 1001.1658102

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By JoAnn Lindman
JoAnn Lindman

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By
JoAnn Lindman

Dear Examiner:

The pending claims were originally added on May 2, 2003, along with a request for an interference with then pending applicant ser. no. 09/896,435 to Boylan et al. The claims were restricted out as directed toward non-elected subject matter and Boylan et al. subsequently issued as U.S. patent no. 6,602,272. Applicant has therefore filed a divisional application directed towards the inventions of the claims of May 2, 2003 and hereby requests to have an interference declared between the above-captioned application and U.S. Patent No. 6,602,272 to Boylan et al., which issued August 5, 2003.

Applicant therefore proposes the following 21 counts:

1. A medical device for use in a body lumen, comprising a self-expanding body formed from struts having a compressed state and an expanded state, the body including a cold formed nickel-titanium alloy having a transformation temperature greater than a mammalian body temperature, wherein the nickel-titanium alloy exhibits linear pseudoelasticity regardless of stress applied to the body, and a sheath at least partially enclosing the body in the compressed state.

2. The medical device of claim 1, wherein the transformation temperature includes at least one of A.sub.s and A.sub.f that is >37 degrees C.

3. The medical device of claim 1, wherein the body has been heat treated and a hysteresis curve of the nickel-titanium alloy does not include a stress plateau.

4. The medical device of claim 1, wherein the nickel-titanium alloy is pseudo elastic when stressed without onset of stress-induced martensite.

5. The medical device of claim 1, wherein the body assumes a shape imparted by cold forming.

6. The medical device of claim 5, wherein the cold forming occurs below the recrystallization temperature of the alloy.

7. The medical device of claim 1, wherein the body includes a thin wall.

8. The medical device of claim 1, wherein the nickel-titanium alloy includes a ternary element selected from the group of chemical elements consisting of: palladium,

platinum, chromium, iron, cobalt, vanadium, manganese, boron, copper, aluminum, tungsten, tantalum, or zirconium.

9. The medical device of claim 1, wherein the nickel-titanium alloy does not undergo a phase transformation when the body is stressed.

10. A medical device for use in a body lumen, comprising a self-expanding body formed from struts, the body including a cold formed nickel-titanium alloy, wherein the nickel-titanium alloy is in a martensitic phase when the body is stressed into a first shape and when the body is stress relieved to a second shape, and wherein the nickel-titanium alloy has a transformation temperature >37 degrees C., and a sheath at least partially enveloping the body in its first shape.

11. The medical device of claim 10, wherein the nickel-titanium alloy does not include stress-induced martensite in the first shape, the second shape, and transitioning therebetween.

12. The medical device of claim 10, wherein a stress-strain hysteresis curve for the nickel-titanium alloy does not include a stress plateau.

13. The medical device of claim 10, wherein the body includes a thin wall and includes an opening therethrough.

14. The medical device of claim 10, wherein the body includes low temperature heat treating.

15. The medical device of claim 14, wherein the heat treating includes heating the alloy up to 350 degrees C. inclusive for up to five minutes inclusive.

16. A method of providing a medical device for use in a body lumen, comprising providing struts including a cold formed nickel-titanium alloy,

setting a transformation temperature >37 degrees C., cold forming the struts into a body having a shape, stressing the body into a first shape wherein the nickel-titanium alloy is in a martensitic phase, providing a sheath, disposing the body in the first shape at least partially inside the sheath, and deploying the body from the sheath to stress relieve the body into a second shape, wherein the nickel-titanium alloy remains in the martensitic phase.

17. The method of claim 16, wherein the method includes stressing the body into the first shape and at least partially withdrawing the body into the sheath.

18. The method of claim 16, wherein stressing the body into the first shape does not create stress-induced martensite in the alloy.

19. The method of claim 16, wherein the transformation temperature includes A.sub.s >37 degrees C.

20. The method of claim 16, wherein the nickel-titanium alloy exhibits linear pseudoelasticity when stressed.

21. The method of claim 16, wherein the nickel-titanium alloy includes a ternary element selected from the group of chemical elements consisting of: palladium, platinum, chromium, iron, cobalt, vanadium, manganese, boron, copper, aluminum, tungsten, tantalum, or zirconium.

The following chart identifies the claims from Boylan et al. and the claims from the above captioned application which correspond to each count.

Count No.	Boylan et al. claim no.	Application claim no.
1	1	38
2	2	39
3	3	40
4	4	41
5	5	42
6	6	43
7	7	44
8	8	45
9	9	46
10	10	47
11	11	48
12	12	49
13	13	50
14	14	51
15	15	52
16	16	53
17	17	54
18	18	55
19	19	56
20	20	57
21	21	58

The following charts are claim charts applying the terms of the application claims identified as corresponding to a count to the disclosure of the application, pursuant to 37 C.F.R. §1.607(a)(5).

Claim 38

A medical device for use in a body lumen, comprising	"The device is designed to traverse through narrow passages within the body and to open within those passages to retrieve the foreign object." Page 1, lines 4-6.
a self-expanding body formed from struts having a compressed state and an expanded state,	Figure 3, "In use, such a device must be able to collapse into a relatively narrow space for traversal purposes and to expand in that space for retrieval purposes." Page 6, lines 10-12.

the body including a cold formed nickel-titanium alloy having a transformation temperature greater than a mammalian body temperature, wherein the nickel-titanium alloy exhibits linear pseudoelasticity regardless of stress applied to the body,	"A precursor alloy material exhibits the stress-strain characteristics shown in Figure 1b." Page 8, lines 3-4. Figure 1b depicts linear pseudoelastic behavior. "[T]he precursor alloy is in a martensitic phase at room temperature to body temperature. The precursor alloy can be a precursor Nitinol…" Page 11, lines 13-15. Nitinol is a nickel-titanium alloy.
and a sheath at least partially enclosing the body in the compressed state.	"Coupling tube 8 also could take the form of a cannula, in which case basket 6 would retract into the cannula prior to retrieval." Page 12, lines 13-14.

Claim 39

The medical device of claim 38 wherein the transformation temperature includes at least one of A.sub.s and A.sub.f that is >37 degrees C.	A transformation temperature greater than 37 degrees Celsius is inherent when "the precursor alloy is in a martensic phase at room to body temperature". Page 11, lines 13-14.

Claim 40

The medical device of claim 38 wherein the body has been heat treated and a hysteresis curve of the nickel titanium alloy does not include a stress plateau.	"[A] nosepiece can be laser welded…to the end of basket 6 to guide device 5 through the body. It is important that during welding or other connecting operations involving heat, that temperature is controlled to prevent heat treating the cable such that precursor alloys are converted to superelastic materials." Page 13, line 21 through page 14, line 5. Heat treatment is inherent in the laser weld process. A nickel titanium precursor alloy which is not converted to a superelastic alloy does not include a stress plateau.

Claim 41

The medical device of claim 38, wherein the nickel-titanium alloy is pseudo elastic when stressed without onset of stress-induced martensite.	"A precursor alloy material exhibits the stress-strain characteristics shown in Figure 1b." Page 8, lines 3-4. "[T]he precursor alloy is in a martensitic phase at room temperature to body temperature." Page 11, lines 13-14. Pseudoelasticity and absence of stress-induced martensite when stressed

	are inherent in a nickel titanium precursor alloy.

Claim 42

The medical device of claim 38, wherein the body assumes a shape imparted by cold forming.	"Several cables...are then bent past the yield point of either the precursor alloy or stainless steel to form basket 6." Page 13, lines 15-16. Cold forming is inherent in this process.

Claim 43

The medical device of claim 42, wherein the cold forming occurs below the recrystallization temperature of the alloy.	Plastic deformation below the recrystallization temperature is the definition of cold forming and therefore inherent in the process.

Claim 44

The medical device of claim 38, wherein the body includes a thin wall.	"Coupling tube 8 also could take the form of a cannula, in which case basket 6 would retract into the cannula prior to retrieval." Page 12, lines 13-14. A cannula would have a thin wall.

Claim 45

The medical device of claim 38, wherein the nickel-titanium alloy includes a ternary element selected from the group of chemical elements consisting of: palladium, platinum, chromium, iron, cobalt, vanadium, manganese, boron, copper, aluminum, tungsten, tantalum, or zirconium.	"Such other precursor alloys that may be used include, for example,...Nickel-Titanium-Vanadium, Iron-Nickel-Titanium-Cobalt..." Page 11, lines 16-20.

Claim 46

The medical device of claim 38, wherein the nickel-titanium alloy does not undergo a phase transformation when the body is stressed.	Not undergoing a phase transformation is inherent in precursor alloys.

Claim 47

A medical device for use in a body lumen	"The device is designed to traverse through narrow passages within the body and to open within those passages to retrieve the foreign object." Page 1, lines 4-6.
comprising a self-expanding body formed	Figure 3, "In use, such a device must be

from struts, the body including a cold formed nickel-titanium alloy, wherein the nickel-titanium alloy is in a martensitic phase when the body is stressed into a first shape and when the body is stress relieved to a second shape, and wherein the nickel-titanium alloy has a transformation temperature >37 degrees C.	able to collapse into a relatively narrow space for traversal purposes and to expand in that space for retrieval purposes." Page 6, lines 10-12. "A precursor alloy material exhibits the stress-strain characteristics shown in Figure 1b." Page 8, lines 3-4. Figure 1b depicts linear pseudoelastic behavior. "[T]he precursor alloy is in a martensitic phase at room temperature to body temperature. The precursor alloy can be a precursor Nitinol..." Page 11, lines 13-15. Nitinol is a nickel-titanium alloy.
and a sheath at least partially enveloping the body in its first shape	"Coupling tube 8 also could take the form of a cannula, in which case basket 6 would retract into the cannula prior to retrieval." Page 12, lines 13-14.

Claim 48

The medical device of claim 47, wherein the nickel-titanium alloy does not include stress-induced martensite in the first shape, the second shape, and transitioning therebetween.	This is inherent in a precursor alloy such as a precursor nickel-titanium alloy. Only if the alloy was treated to become superelastic would stress induce martensite.

Claim 49

The medical device of claim 47, wherein a stress-strain hysteresis curve for the nickel-titanium alloy does not include a stress plateau.	"A precursor alloy material exhibits the stress-strain characteristics shown in Figure 1b." Page 8, lines 3-4. Figure 1b does not depict a stress plateau.

Claim 50

The medical device of claim 47, wherein the body includes a thin wall and includes an opening therethrough.	"Coupling tube 8 also could take the form of a cannula, in which case basket 6 would retract into the cannula prior to retrieval." Page 12, lines 13-14.

Claim 51

The medical device of claim 47, wherein the body includes low temperature heat treating.	"[A] nosepiece can be laser welded...to the end of basket 6 to guide device 5 through the body. It is important that during welding or other connecting operations involving heat, that temperature is controlled to prevent heat treating the cable such that precursor alloys are converted to superelastic materials." Page 13, line 21 through page 14, line 5. Heat treatment is

	inherent in the laser weld process.

Claim 52

The medical device of claim 51, wherein the heat treating includes heating the alloy up to 350 degrees C. inclusive for up to five minutes inclusive.	"[A] nosepiece can be laser welded…to the end of basket 6 to guide device 5 through the body. It is important that during welding or other connecting operations involving heat, that temperature is controlled to prevent heat treating the cable such that precursor alloys are converted to superelastic materials." Page 13, line 21 through page 14, line 5. Heat treatment is inherent in the laser weld process.

Claim 53

A method of providing a medical device for use in a body lumen, comprising	"The device is designed to traverse through narrow passages within the body and to open within those passages to retrieve the foreign object." Page 1, lines 4-6.
providing struts including a cold formed nickel-titanium alloy,	Figure 3, "In use, such a device must be able to collapse into a relatively narrow space for traversal purposes and to expand in that space for retrieval purposes." Page 6, lines 10-12.
setting a transformation temperature >37 degrees C.,	A transformation temperature greater than 37 degrees Celsius is inherent when "the precursor alloy is in a martensic phase at room to body temperature". Page 11, lines 13-14.
cold forming the struts into a body having a shape,	"Several cables…are then bent past the yield point of either the precursor alloy or stainless steel to form basket 6." Page 13, lines 15-16. Cold forming is inherent in this process.
stressing the body into a first shape wherein the nickel-titanium alloy is in a martensitic phase,	Figure 3, "In use, such a device must be able to collapse into a relatively narrow space for traversal purposes and to expand in that space for retrieval purposes." Page 6, lines 10-12. A nickel-titanium precursor alloy is in a non-stress induced martensitic phase.
providing a sheath,	"Coupling tube 8 also could take the form of a cannula, in which case basket 6 would retract into the cannula prior to retrieval." Page 12, lines 13-14.

disposing the body in the first shape at least partially inside the sheath, and	"Coupling tube 8 also could take the form of a cannula, in which case basket 6 would retract into the cannula prior to retrieval." Page 12, lines 13-14.
deploying the body from the sheath to stress relieve the body into a second shape, wherein the nickel-titanium alloy remains in the martensitic phase.	Figure 3, "In use, such a device must be able to collapse into a relatively narrow space for traversal purposes and to expand in that space for retrieval purposes." Page 6, lines 10-12. A alloy in a non-stress induced martensitic phase remains in a martensitic phase when stress relieved into second shape.

Claim 54

The method of claim 53, wherein the method includes stressing the body into the first shape and at least partially withdrawing the body into the sheath.	"Coupling tube 8 also could take the form of a cannula, in which case basket 6 would retract into the cannula prior to retrieval." Page 12, lines 13-14.

Claim 55

The method of claim 53, wherein stressing the body into the first shape does not create stress-induced martensite in the alloy.	This is inherent in a nickel-titanium precursor alloy.

Claim 56

The method of claim 53, wherein the transformation temperature includes A.sub.s >37 degrees C.	A transformation temperature greater than 37 degrees Celsius is inherent when "the precursor alloy is in a martensic phase at room to body temperature". Page 11, lines 13-14.

Claim 57

The method of claim 53, wherein the nickel-titanium alloy exhibits linear pseudoelasticity when stressed.	"A precursor alloy material exhibits the stress-strain characteristics shown in Figure 1b." Page 8, lines 3-4. Figure 1b depicts linear pseudoelastic behavior.

Claim 58

The method of claim 53, wherein the nickel-titanium alloy includes a ternary element selected from the group of chemical elements consisting of: palladium, platinum, chromium, iron, cobalt, vanadium, manganese, boron, copper, aluminum, tungsten, tantalum, or zirconium.	"Such other precursor alloys that may be used include, for example,...Nickel-Titanium-Vanadium, Iron-Nickel-Titanium-Cobalt..." Page 11, lines 16-20.

Applicant requests consideration of this request for an interference with a patent. Applicant would remind the examiner that, under 37 C.F.R. § 1.307(b), "when an applicant seeks an interference with a patent, examination of the application...shall be conducted with special dispatch within the Patent and Trademark Office." If the undersigned can be of assistance to the examiner, please contact him at 612-677-9050.

Respectfully Submitted,

GARY B. MCALISTER

By his Attorney

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